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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/611,588 | 06/30/2003 | Avigdor Levanon | 10793/70 | 5130 |

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KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

| EXAMINER | |
|---|---|
| GAMBEL, PHILLIP | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | 5 |
|---|---|---|---|
| | 10/611,588 | LEVANON ET AL. | |
| | Examiner | Art Unit | |
| | Phillip Gambel | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-85* is/are pending in the application.

4a) Of the above claim(s) *80 and 81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-79, 82-85* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 1-85 are pending.

2. It is noted that claims 80-81 are directed to the "use" of a composition. "Use" claims are non-statutory under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki , 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd v. Brenner,255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP 2173.05(q).

Therefore, claims 80-81 have been withdrawn from consideration as being drawn to non-statutory subject matter. If these claims are amended to recite statutory subject matter, the amended claims may be rejoined with the appropriate invention Group as set forth below.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-33, 46-48, 82-83, 85, drawn to PSGL-1-specific antibodies and compositions / kits thereof, classified in Class 424, subclass 130.1; Class 435, subclass 810 and Class 530, subclass 387.1.

II. Claims 34-38, drawn to isolated epitopes, classified in Class 514, subclass 2.

III. Claims 39-45, drawn to nucleic acids encoding PSGL-1-specific antibodies, vectors, host cells and methods of producing an antibody, classified in Class 536, subclass 23.53, Class 435, subclasses 69.6, 252.3, 320.1, 326.

IV. Claims 49-69, drawn to methods of administering PSGL-1-specific antibodies, classified in Class 424, subclass 143.1.

V. Claims 70-77, drawn to methods of diagnosing or staging a disease with PSGL-1 specific antibodies, classified in Class 435, subclass 7.1.

VI. Claims 78-79, drawn to methods of purging tumor cells with PSGL-1-specific antibodies ex vivo, classified in Class 424, subclass 9.1.

VII. Claim 84, drawn to methods of producing an antibody via a phage display library, classified in Class 435, subclass .

4. Inventions I-VII are directed to related products or processes associated with PSGL-1-specific antibodies. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j).

In the instant case, the inventions as claimed are distinct for the reasons set forth herein. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5. Inventions I and IV / V / VI are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the products as claimed can be used in a materially different processes such as affinity purification and detection assays as well as the other methods indicated above.

Also, the methods of treating, diagnosing, staging or purging cann be achieved a host of agents other than the claimed PSGL-1-specific antibodies.

6. Inventions III, IV, V, VI, VIII are different methods, which require different ingredients, process steps and endpoints. Therefore, they are patentably distinct.

7. Inventions I, II and III are different products. Antibodies, nucleic acids, host cells, vectors and epitopes are distinct because they differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. The examiner notes that these molecules do not share a substantial structural feature essential to a common utility. Therefore, they are patentably distinct.

8. Inventions I and III / VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case, antibodies can be made via a variety of biochemical and recombinant means as well as standards methods of immunization protocols that do not rely upon expressing nucleic acids encoding antibodies or selection via phage display.

9. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-VII is not required for any other group from Groups I-VII and Groups I-VII have acquired a separate status in the art because the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

10. In addition to electing a Group from above,
this application contains claims directed to the following patentably distinct species of the claimed Groups I, IV, V and VI: wherein the PSGL-1-specific antibody
A) is not conjugated or complexed with an agent or
B) is conjugated or complexed with an agent set forth in claims 19-31.

*If (B) is elected, then applicant should also elect a vehicle or carrier set forth in claims 32-33.*

Antibody and antibody conjugates as well as the agents differ from one another in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. The examiner notes that these molecules do not share a substantial structural feature essential to a common utility.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (*e.g. unconjugated or acyclovir and liposomes*) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

11. In addition to electing a Group and the species from above,
If Group I, III, IV, V or VI is elected from above,
this application contains claims directed to the following patentably distinct species of the claimed Groups : wherein applicant is further required to elect one particular antibody that binds PSGL-1 and to provide the following information with respect to the elected epitope and corresponding CDRs of a functional PSGL-1-specific antibody:

Applicant is required to select the appropriate heavy chain CDR SEQ ID NOS. and appropriate epitopes set forth in claims 1-18.

These species of the antibody that binds PSGL-1 epitopes are distinct because each antibody possesses a unique structure as determined both by its heavy and light chain sequences, including the CDRs. Further, the examination of these species would require different searches in the scientific literature and electronic databases. As such, it would be burdensome to search these species together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall

12. In addition to electing a Group and species from above,
this application contains claims directed to the following patentably distinct species of the claimed Groups IV and V: wherein the disease is selected from claims 49-77 or page 40 of the instant specification.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

13. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

*Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.*

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

16. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, Ph.D., J.D.
Primary Examiner
Technology Center 1600
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